DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 16, 2015

HHSsystems, LLC
c/o Jane B. Campbell
164 Hammock Avenue
Pawleys Island, SC 29585

Re: K142551
Trade/Device Name: QANS (quantitative Autonomic Nervous System) Monitoring System
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS, BZQ, KZM
Dated: March 6, 2015
Received: March 9, 2015

Dear Ms. Campbell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-

related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Revised Indications for Use Statement

510(k) Number: K142551

Device Name: QANS (Quantitative Autonomic Nervous System) Monitoring System

Indications for Use:

The intended use of the HHSsystems QANS (Quantitative Autonomic Nervous System) Monitoring System:

QANS (Quantitative Autonomic Nervous System) Monitoring System is a physiological monitoring device that collects and transmits measurements (heart rate, respiration rate, and muscle activity) using sensors. The QANS monitoring system monitors the sympathetic and parasympathetic nervous system using accurate recordings of heart rate (HR) from EKG and provides statistical data as well as heart rate variability (HRV) data which the clinician can use it make clinical assessments of medical, dental or peak performance interventions.

The physiological information can be used as a general patient monitoring system as well as for research. QANS is not intended to produce any interpretation of the measurements obtained and does not provide any type of diagnosis.

Patients should be 5 years old or older.

Prescription Use __X_____ AND/OR Over-The Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____
(Division Sign-Off)

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of Section 513(i)(3) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. 807.92.

Date:	April 13, 2015
Sponsor:	HHSsystems, LLC 2 Executive Blvd, Suites 206 Suffern, NY 10901 Howard G. Hindin, DDS Telephone: 845-357-1595 Fax : 845-357-2428 E-mail : hindincenter@verizon.net
Contact:	Jane B. Campbell 164 Hammock Avenue Pawleys Island, SC 29585 Tel: (843) 314-3670 Email: jane.campbell@campbellassociates.net
Trade Name:	QANS (Quantitative Autonomic Nervous System) Monitoring System
Common Name:	HRV Monitoring System Respiration Rate Monitoring System Muscle Activity Monitoring System
Classification Name:	Electrocardiograph Breathing Frequency Monitor (Respiration Rate) Electromyograph
Classification Number:	Electrocardiograph 21 C.F.R. 870.2340 DPS, Class II. Breathing Frequency Monitor (Respiration Rate) 21 C.F.R. 868.2375, BZQ, Class II. Electromyograph 21 C.F.R. 890.1375, KZM, Class II.
Product Codes:	DPS, BZQ, KZM

Predicate Devices:

QANS (Quantitative Autonomic Nervous System) Monitoring System is substantially equivalent to the following predicate devices:

For safety and accuracy

1. Thought Technology ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp 2 Encoder systems --K903497.
2. using BioGraph Infiniti and CardioPro software -- K972723.

Note: All of the parameters that are recorded by the QANS system are recorded by the Thought Technology devices.

For monitoring functions:

1. HeRO ™ HRV analysis system (510(k) K021230).
2. Intelwave Heart Rate Variability System (510(k) K062068)

Device Description:

The HHSsystems QANS Monitoring System is the same as that of the Thought Technology devices as the HHSsystems QANS uses the same hardware as the previously cleared ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp2 devices with the same BioGraph Infiniti and CardioPro software.

This information is contained in 510(k)'s K903497 for the ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp2 and in K972723 for the BioGraph Infiniti and CardioPro software.

The technology and the method of monitoring heart rate, respiration rate, and muscle activity, are essentially the same as those of the other legally marketed predicate devices.

QANS (Quantitative Autonomic Nervous System) Monitoring System is a computer-based system for measurement of Heart Rate Variability (HRV) in response to paced respiration. It is comprised of off-the-shelf Personal Computers (PCs) and special purpose hardware capable of acquiring, storing, analyzing and reporting ECG data from cardiac monitoring devices, respiration rate and muscle activity, using sensors designed to monitor these functions. Data is acquired using the Thought ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp2 and in K972723 for the BioGraph Infiniti and CardioPro software.

	The analysis algorithms identify heart rate variability (HRV) patterns that reflect transient decelerations and/or reduced baseline variability. QANS evaluates the variation of the heart rate, both in the time domain (statistical methods) and in the frequency domain (spectral analysis). Each QRS complex (Q, R and S wave deflections on a ECG) detected and the so-called normal-to-normal (NN) or Rate-to-Rate (RR) intervals between adjacent QRS complexes are resulting from sinus node depolarization. The system performs a fully automated quantitative analysis of HRV based on data collected by an FDA-compliant R Wave Trigger device. The system presents the results to the healthcare provider through a computer-based user interface. The system has patient data management capability.
Intended use:	QANS (Quantitative Autonomic Nervous System) Monitoring System is a physiological monitoring device that collects and transmits measurements (heart rate, respiration rate, muscle activity) using sensors. The QANS monitoring system monitors the sympathetic and parasympathetic nervous system using accurate recordings of heart rate (HR) data from EKG and provides statistical data as well as heart rate variability (HRV) data which the clinician can use it make clinical assessments of medical, dental or peak performance interventions. The physiological information can be used as a general patient monitor as well as for research. QANS is not intended to produce any interpretation of the measurements obtained and does not provide any type of diagnosis. Patients should be 5 years old or older. The QANS System is indicated for use by physicians and dentists in hospital, clinic or professional offices and other health care professionals.
Technological	The technological characteristics of the HHSsystems QANS Monitoring System are the same as those of the Thought Technology devices as the HHSsystems QANS uses the same hardware as the previously cleared FlexComp Infiniti, ProComp Infiniti, ProComp5 and ProComp2 with the BioGraph Infiniti and CardioPro software.

	This information is contained in 510(k)'s K903497 for the ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp2 and in K972723 for the BioGraph Infiniti. The technology and the method of monitoring heart rate, respiration rate, and muscle activity are essentially the same as those of the other legally marketed predicate devices
Technology:	Microprocessor based system
Comparison of Technological the Predicate Devices:	QANS system is identical to the Thought Technology ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp 2 encoders to with BioGraph Infiniti and CardioPro General purpose software as they use the same hardware and software. The sensors and leads are the same and the way the information is gathered, and stored is identical. The QANS application software allows the user to report the information in a manner most suited to the user's needs. There are no new tests and no new results reported. There is a quick start feature and the user can customize the screens and reports. The form of the results report is the only change.
Summary:	The HHSsystems QANS Monitoring System was developed and is based on ProComp Infiniti, FlexComp Infiniti, ProComp5 and ProComp2 with the BioGraph Infiniti and CardioPro software. This system was developed in accordance with 21CFR820 Quality System Regulation and has been tested in accordance with UL 60601-1 and IEC 60601-1-2.
Performance data:	All HHSsystems QANS functionality has been verified and validated both as part of the BioGraph and the QANS application suite.